

MEDICATION GUIDE
RITUXAN[®] (ri-tuk'-san)
(rituximab)
for injection

Read this Medication Guide before you start Rituxan and before each Rituxan infusion. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about Rituxan?

Rituxan can cause serious side effects that can lead to death, including:

- 1. Infusion reactions.** Infusion reactions are the most common side effect of Rituxan treatment. Serious infusion reactions can happen during your infusion or within 24 hours after your infusion of Rituxan. Your doctor should give you medicines before your infusion of Rituxan to decrease your chance of having a severe infusion reaction.

Tell your doctor or get medical help right away if you get any of these symptoms during or after an infusion of Rituxan:

- hives (red itchy welts) or rash
- itching
- swelling of your lips, tongue, throat or face
- sudden cough
- shortness of breath, difficulty breathing, or wheezing
- weakness
- dizziness or feel faint
- palpitations (feel like your heart is racing or fluttering)
- chest pain

- 2. Progressive Multifocal Leukoencephalopathy (PML).** PML is a rare, serious brain infection caused by a virus. People with weakened immune systems can get PML. Your chance of getting PML may be higher if you are treated with Rituxan alone or with other medicines that weaken your immune system. PML can result in death or severe disability. There is no known treatment, prevention, or cure for PML.

Tell your doctor right away if you have any of the following symptoms or if anyone close to you notices these symptoms:

- confusion or problems thinking
- loss of balance
- change in the way you walk or talk
- decreased strength or weakness on one side of your body
- blurred vision or loss of vision

- 3. Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause you to have:

- kidney failure and the need for dialysis treatment
- abnormal heart rhythm

1056 Your doctor may do blood tests to check you for TLS. Your doctor may give you medicine to
1057 help prevent TLS.

1058 **4. Severe skin and mouth reactions.** Tell your doctor or get medical help right away if you get
1059 any of these symptoms at anytime during your treatment with Rituxan:

- 1060 • painful sores or ulcers on your skin, lips or in your mouth
- 1061 • blisters
- 1062 • peeling skin
- 1063 • rash
- 1064 • pustules

1065 See “**What are possible side effects of Rituxan?**” for more information about side effects.

1066 **What is Rituxan?**

1067 Rituxan is a prescription medicine used to treat:

- 1068 • **Non-Hodgkin’s Lymphoma (NHL):** alone or with other chemotherapy medicines.
- 1069 • **Chronic Lymphocytic Leukemia (CLL):** with the chemotherapy medicines fludarabine and
1070 cyclophosphamide.
- 1071 • **Rheumatoid Arthritis (RA):** with another prescription medicine called methotrexate, to reduce
1072 the signs and symptoms of moderate to severe active RA in adults, after treatment with at least
1073 one other medicine called a Tumor Necrosis Factor (TNF) antagonist has been used and did not
1074 work well enough.
- 1075 • **Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA):** with
1076 glucocorticoids, to treat WG and MPA.

1077 People with serious infections should not receive Rituxan.

1078 It is not known if Rituxan is safe or effective in children.

1079
1080 **What should I tell my doctor before receiving Rituxan?**

1081 Before receiving Rituxan, tell your doctor if you:

- 1082 • have had a severe infusion reaction to Rituxan in the past
- 1083 • have a history of heart problems, irregular heart beat or chest pain
- 1084 • have lung or kidney problems
- 1085 • have an infection or weakened immune system.
- 1086 • have or have had any severe infections including:
 - 1087 • Hepatitis B virus (HBV)
 - 1088 • Hepatitis C virus (HCV)
 - 1089 • Cytomegalovirus (CMV)
 - 1090 • Herpes simplex virus (HSV)
 - 1091 • Parvovirus B19
 - 1092 • Varicella zoster virus (chickenpox or shingles)
 - 1093 • West Nile Virus

- 1094 • have had a recent vaccination or are scheduled to receive vaccinations. You should not receive
1095 certain vaccines before or after you receive Rituxan. Tell your doctor if anyone in your
1096 household is scheduled to receive a vaccination. Some types of vaccines can spread to people
1097 with a weakened immune system, and cause serious problems.
- 1098 • have taken Rituxan for WG or MPA in the past.
- 1099 • have any other medical conditions
- 1100 • are pregnant or planning to become pregnant. Rituxan may affect the white blood cell counts of
1101 your unborn baby. It is not known if Rituxan may harm your unborn baby in other ways.
1102 Women who are able to become pregnant should use effective birth-control (contraception)
1103 while using Rituxan and for 12 months after you finish treatment. Talk to your doctor about
1104 effective birth control.
- 1105 • are breast-feeding or plan to breast-feed. It is not known if Rituxan passes into your breast milk.
1106 You and your doctor should decide the best way to feed your baby if you receive Rituxan.

1107 Tell your doctor about all the medicines you take, including prescription and nonprescription
1108 medicines, vitamins, and herbal supplements. Especially tell your doctor if you take or have taken:

- 1109 • a Tumor Necrosis Factor (TNF) inhibitor medicine
- 1110 • a Disease Modifying Anti-Rheumatic Drug (DMARD)

1111 If you are not sure if your medicine is one listed above, ask your doctor or pharmacist.

1112 Know the medicines you take. Keep a list of them to show to your doctor and pharmacist when you
1113 get a new medicine. Do not take any new medicine without talking with your doctor.

1114 **How will I receive Rituxan?**

- 1115 • Rituxan is given by infusion through a needle placed in a vein (intravenous infusion), in
1116 your arm. Talk to your doctor about how you will receive Rituxan.
- 1117 • Your doctor may prescribe medicines before each infusion of Rituxan to reduce side effects
1118 of infusions such as fever and chills.
- 1119 • Your doctor should do regular blood tests to check for side effects to Rituxan.

1120 Before each Rituxan treatment, your doctor or nurse will ask you questions about your general
1121 health. Tell your doctor or nurse about any new symptoms.

1122 **What are the possible side effects of Rituxan?**

1123 Rituxan can cause serious and life-threatening side effects, including:

1124 See **“What is the most important information I should know about Rituxan?”**

- 1125 • **Hepatitis B virus (HBV) reactivation.** If you have had hepatitis B or are a carrier of hepatitis B
1126 virus, receiving Rituxan could cause the virus to become an active infection again. This may
1127 cause serious liver problems including liver failure, and death. You should not receive Rituxan
1128 if you have active hepatitis B liver disease.
- 1129 • **Serious infections.** Serious infections that happen with Rituxan can lead to death. Call your
1130 doctor right away if you have any symptoms of infection:
 - 1131 ○ fever
 - 1132 ○ cold symptoms, such as runny nose or sore throat that do not go away
 - 1133 ○ flu symptoms, such as cough, tiredness, and body aches
 - 1134 ○ earache or headache

- 1135 ○ pain during urination
- 1136 ○ white patches in the mouth or throat
- 1137 ○ cuts, scrapes or incisions that are red, warm, swollen or painful
- 1138 • **Heart problems.** Rituxan may cause chest pain and irregular heart beats which may need
- 1139 treatment, or your doctor may decide to stop your treatment with Rituxan.
- 1140 • **Kidney problems,** especially if you are receiving Rituxan for NHL. Your doctor should do
- 1141 blood tests to check how well your kidneys are working.
- 1142 • **Stomach and Serious bowel problems that can sometimes lead to death.** Bowel problems,
- 1143 including blockage or tears in the bowel can happen if you receive Rituxan with chemotherapy
- 1144 medicines to treat non-Hodgkin's lymphoma. Tell your doctor right away if you have any
- 1145 stomach area pain during treatment with Rituxan.
- 1146 • **Low blood cell counts.** Your doctor may do blood tests during treatment with Rituxan to check
- 1147 your blood cell counts.
- 1148 ○ **White blood cells.** White blood cells fight against bacterial infections. Low white
- 1149 blood cells can cause you to get infections, which may be serious. See "Increased
- 1150 risk of infections" above for a list of symptoms of infection.
- 1151 ○ **Red blood cells.** Red blood cells carry oxygen to your body tissues and organs.
- 1152 ○ **Platelets.** Platelets are blood cells that help your blood to clot.

1153 **Common side effects during Rituxan treatment include:**

- 1154 • infusion reactions (see What is the most important information I should know about Rituxan?)
- 1155 • chills
- 1156 • infections
- 1157 • body aches
- 1158 • tiredness
- 1159 • low white blood cells

1160 Other side effects with Rituxan include:

- 1161 • aching joints during or within hours of receiving an infusion
- 1162 • more frequent upper respiratory tract infection

1163 Tell your doctor about any side effect that bothers you or that does not go away.

1164 These are not all of the possible side effects with Rituxan. For more information, ask your doctor or

1165 pharmacist.

1166 Call your doctor for medical advice about side effects. You may report side effects to FDA at

1167 1-800-FDA-1088.

1168 **General information about Rituxan**

1169 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This

1170 Medication Guide provides a summary of the most important information about Rituxan. If you

1171 would like more information, talk with your doctor. You can ask your doctor for information about

1172 Rituxan that is written for healthcare professionals.

1173 For more information, go to www.Rituxan.com or call 1-877-474-8892.

1174 **What are the ingredients in Rituxan?**
1175 Active ingredient: rituximab
1176 Inactive ingredients: sodium chloride, sodium citrate dihydrate, polysorbate 80, and water for
1177 injection.
1178 Jointly Marketed by: Biogen Idec Inc. and Genentech USA, Inc.
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RITUXAN® [rituximab]
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1 DNA Way Rituxan® is a registered trademark of Biogen Idec, Inc.
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1181 This Medication Guide has been approved by the U.S. Food and Drug Administration.